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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA

PHYSICIANS RECOMMENDED NUTRICEUTICALS, LLC,	)	
Plaintiff,	)	CIVIL ACTION NO.:
v.	)	JURY TRIAL DEMANDED
LUNOVUS, LLC	)	
and	)	
JOHN DOES 1-10,	)	
Defendants.	)	

VERIFIED COMPLAINT FOR PATENT INFRINGEMENT, UNFAIR COMPETITION, DECEPTIVE TRADE PRACTICES, DAMAGES AND INJUNCTIVE RELIEF

Plaintiff, Physicians Recommended Nutriceuticals, LLC, by and through its undersigned attorney, for its Complaint for Patent Infringement, Unfair Competition, Deceptive Trade Practices, Damages and Injunctive Relieve against Defendants Lunovus, LLC (hereinafter "Lunovus") and John Does 1-10, demands a jury trial, and alleges as follows:

PARTIES

1. Plaintiff, Physicians Recommended Nutriceuticals, LLC (hereinafter "PRN"), is a limited liability company organized and existing under the laws of the state of Delaware having a principal place of business at 5 Sentry Parkway East, Suite 210, Blue Bell, PA 19422. PRN is licensed to transact business in the state of Pennsylvania and it sells goods throughout the United States, including the State of Alabama and this Judicial District.

2. PRN makes, markets, formulates, designs, manufactures, advertises, distributes and sells a wide range of health and wellness related products. PRN is well known as an innovative leader in the nutriceutical industry for developing and delivering products for improving macular health and, more specifically, the conditions associated with dry eye, blepharitis and/or inflamed or dysfunctional meibomian glands within the state of Pennsylvania and throughout the United States.

3. On information and belief, Defendant Lunovus is a limited liability company organized and existing under the laws of the state of Alabama having a principal place of business at 8289 Highway 31 N., Morris, Alabama 35116. Lunovus is, and was at all times pertaining to this Complaint, transacting business in the State of Alabama and in this Judicial District.

4. Lunovus has for a time past and still is making, using, selling and/or offering for sale, nutriceutical products that are protected by U.S. Patent No. 9,115,078 (hereinafter sometimes referred to as the "'078 Patent") and U.S. Patent No. 9,381,183 entitled "Methods for Improving the Quality of the Meibum Composition of Meibomian Glands" (hereinafter sometimes referred to as the "'183 Patent") owned by PRN. This ongoing and continuous infringing activity is occurring, directly and/or through intermediaries, throughout the United States, including this Judicial District.

5. Lunovus has for a time past and still is falsely advertising the creation and development of a formula for nutriceutical products which was copied from Plaintiff's patented nutriceutical products. This ongoing and continuous infringing activity is occurring, directly and/or through intermediaries, throughout the United States, including this Judicial District.

6. On information and belief, Defendant JOHN DOES 1-5 include agents, distributors, retailers, consultants and all persons or entities acting in concert or under the direction of Lunovus in making, using, marketing, advertising, selling and/or offering for sale an infringing TEAR SUPPORT PLUS + product either directly or contributorily and, by doing so, are participating in the alleged acts of unfair competition and/or deceptive trade practices. The proper identities of JOHN

DOES 1-5 are unknown to the Plaintiff at this time. PRN will seek to amend this Complaint to show the true name of Defendant JOHN DOES 1-5 when they have been ascertained.

7. On information and belief, Defendant JOHN DOES 5-10 include previous customers of PRN and some Doctors that may have sat on PRN's Advisory Board, whereby having access to certain proprietary insights related to the development and formulations of the compositions and methods for using the same that are claimed in the PRN Patents and, accordingly, assisting Lunovus in making, using, marketing, advertising, selling and/or offering for sale the infringing TEAR SUPPORT PLUS + product and, by doing so, inducing and/or participating in the alleged acts of unfair competition and/or deceptive trade practices. The proper identities of JOHN DOES 5-10 are unknown to the Plaintiff at this time. PRN will seek to amend this Complaint to show the true name of Defendant JOHN DOES 5-10 when these persons have been ascertained.

JURISDICTION & VENUE

8. This in an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and are brought to redress the

infringement by Defendants of United States Patent Nos. 9,115,078 and 9,381,183 (collectively, the "PRN Patents").

9. Jurisdiction over the claims asserted in this Complaint arises under 28 U.S.C. § 1331 in that this action involves a federal question. Jurisdiction over the claims also arises under 28 U.S.C. § 1338 in that this action arises under the patent laws of the United States.

10. On information and belief, Defendants are subject to personal jurisdiction in the Northern District of Alabama (the "District"), consistent with the principles of due process, and because Defendants are a limited liability company incorporated in the state of Alabama having a principal place of business in the District, and Defendants have participated in the sale and/or offer to sale the infringing TEAR SUPPLY PLUS + products in this District, have transacted business in this District, have committed and/or induced acts of patent infringement in this District, have placed infringing products into the stream of commerce through established distribution channels with the expectation that such products will be purchased by residents of this District, and/or have participated in tortious acts of unfair competition and/or deceptive trade practices in this District.

11. Venue is proper in this District under 28 U.S.C. §§ 1391(b), 1391(c), 1391(d) and 1400(b). Upon information and belief, Defendants are doing business

in this District. Defendants have committed tortious acts in this District, including infringement of the ’078 Patent and the ’183 Patent and engagement in acts of unfair competition and deceptive trade practices.

GENERAL ALLEGATIONS

12. On August 25, 2015, U.S. Patent No. 9,115,078, entitled “Compositions for Improving the Quality of the Meibum Composition of Inflamed or Dysfunctional Meibomian Glands” was issued by the U.S. Patent and Trademark Office to PRN. PRN is the owner of all right, title and interest in the ’078 Patent. A true copy of the ’078 Patent is attached hereto as Exhibit A and incorporated herein by reference.

13. The invention described and claimed in the ’078 Patent is directed to compositions consisting of a single fatty acid for improving the quality of the meibum composition of inflamed or dysfunctional meibomian glands, wherein the fatty acid consists of omega-3 fatty acids in the triglyceride form in an amount greater than 600 mg. In addition, the compositions may further include vitamin D.

14. On July 5, 2016, U.S. Patent No. 9,381,183, entitled “Compositions for Improving the Quality of the Meibum Composition of Inflamed or Dysfunctional Meibomian Glands” was issued by the U.S. Patent and Trademark Office to PRN.

PRN is the owner of all right, title and interest in the ’183 Patent. A true copy of the ’183 Patent is attached hereto as Exhibit B and incorporated herein by reference.

15. The invention described and claimed in the ’183 Patent is directed to methods for improving the quality of the meibum composition of inflamed or dysfunctional meibomian glands, comprising the steps of (1) administering an effective amount of omega-3 fatty acids on a daily dosage basis, wherein the omega-3 fatty acids include eicosapentaenoic acid (EPA) in an amount greater that 600 mg and comprising the triglyceride form; (2) increasing levels of anti-inflammatory omega-3's in a composition of meibum of the treated meibomian glands and (3) decreasing levels of inflammatory omega-6's in the composition of meibum. The methods of the present invention may further comprise the following steps: (1) improving tear break up time; (2) reducing tear osmolarity and/or (3) improving the quality of tears associated with conditions of dry eye, blepharitis and/or meibomianitis.

16. Lunovus is a competitor of PRN in the nutriceutical industry. Lunovus has for a time past and still is making, using, offering for sale and/or selling a product called TEAR SUPPORT PLUS +. A true copy of advertising and marketing information associated with the promotion of the TEAR SUPPORT PLUS + product by Lunovus can be found at www.amazon.com and then searching

for “tear support plus lunovus.” http://www.ast The true copy of the referenced advertising and marketing information is attached hereto as Exhibit C and incorporated herein by reference.

17. The TEAR SUPPORT PLUS + product is described in the PRN Patents and falls within the scope of one or more claims of the ’078 Patent and the ’183 Patent. Lunovus has manufactured the infringing TEAR SUPPORT PLUS + product within the United States and has used, sold, offered for sale and/or distributed this product throughout the United States and within this Judicial District.

18. Defendants are directly infringing and/or inducing others to infringe by making, using, offering to sell and/or selling in the United States, and/or importing into the United States, products or processes that practice one or more inventions that are claimed in the PRN Patents.

19. Defendants have profited through infringement of the PRN Patents. As a result of Defendants unlawful infringement of the PRN Patents, PRN has suffered and will continue to suffer damage. PRN is entitled to recover from Defendants the damages suffered by PRN as a result of Defendants’ unlawful acts.

20. Defendants have willfully and knowingly prepared and advertised a Product Description that is found at www.amazon.com which falsely declares that Lunovus developed the formulation for the infringing TEAR SUPPORT PLUS + product. However, the infringing Lunovus product is identical to the formulation of PRN's patented product, which is evidenced by the substantially identical "Supplement Facts" label of both, PRN's patented product and Lunovus' infringing product.

21. Defendants have profited through the false advertising of the of the infringing TEAR SUPPORT PLUS + product. As a result of Defendants unlawful false advertising and unfair competition, PRN has suffered and will continue to suffer damage. PRN is entitled to recover from Defendants the damages suffered by PRN as a result of Defendants' unlawful acts.

22. The activities of Defendants have caused and will continue to cause substantial damage, including lost revenues, to PRN and irreparable injury for which PRN has no adequate remedy at law. PRN derives substantial revenues from its products that fall within the scope of one or more claims of the PRN Patents. PRN has expended considerable sums of money in developing and marketing this technology. The existence in the market of the Lunovus' TEAR SUPPORT PLUS

+ product is causing, and will in the future cause, substantial damage to PRN. In order to prevent further irreparable harm, PRN seeks a preliminary and permanent injunction and requests that the Court promptly schedule a trial on the merits.

23. On information and belief, Defendants' infringement of one or more of the PRN Patents is willful and deliberate, entitling PRN to enhanced damages and reasonable attorney fees and costs.

24. On information and belief, Defendants intend to continue their unlawful infringing activity, and PRN continues to and will continue to suffer irreparable harm – for which there is no adequate remedy at law – from such unlawful infringing activity unless Defendants are enjoined by this Court.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 9,115,078

25. PRN re-alleges and incorporates by reference the allegations set forth in paragraphs 1 through 24.

26. PRN is the owner of all right, title and interest in the '078 Patent.

27. The invention described and claimed in the '078 Patent is directed to compositions consisting of a single fatty acid for improving the quality of the

meibum composition of inflamed or dysfunctional meibomian glands, wherein the fatty acid consists of omega-3 fatty acids in the triglyceride form in an amount greater than 600 mg. In addition, the compositions disclosed and claimed in the ’078 Patent may further include docosahexaenoic acid (DHA) in an amount greater than 500 mg and/or vitamin D in an amount between 500 IU and 2,000 IU.

28. A copy of the ingredients comprising the composition of PRN’s patented OMEGA BENEFITS® product, sometimes also referred to and promoted as PRN’s patented DRY EYE OMEGA BENEFITS product, is identified on the product label as the “Supplement Facts,” attached hereto as Exhibit D and incorporated herein by reference.

29. A copy of the ingredients comprising the composition of Lunovus’ TEAR SUPPORT PLUS + product is identified on the product label as the “Supplement Facts,” attached hereto as Exhibit C and incorporated herein by reference.

30. Upon review of the “Supplement Facts” for the infringing TEAR SUPPORT PLUS + product, it is clear that the formulation of the TEAR SUPPORT PLUS + product includes the identical ingredients and dosage amounts as compared

to the ingredients and dosage amounts of the formulation of the composition disclosed and claimed in the ’078 Patent.

31. Defendants have been and/or are directly infringing and/or inducing the infringement of and/or contributorily infringing the ’078 Patent by, among other things, making, using, offering to sell or selling in the United States, or importing into the United States, products that are covered by at least one or more claims of the ’078 Patent, including, by way of example and not limitation, the TEAR SUPPORT PLUS + product.

32. The activities of Defendants have caused and will continue to cause substantial damage, including lost revenues, to PRN and irreparable injury for which PRN has no adequate remedy at law. PRN derives substantial revenues from its products that fall within the scope of one or more claims of the ’078 Patent. PRN has expended considerable sums of money in developing and marketing this technology. The existence in the market of the Lunovus TEAR SUPPORT PLUS + product is causing, and will in the future cause, substantial damage to PRN. In order to prevent further irreparable harm, PRN seeks a preliminary and permanent injunction and requests that the Court promptly schedule a trial on the merits.

33. On information and belief, Defendants' infringement of one or more of the '078 Patent is willful and deliberate, entitling PRN to enhanced damages and reasonable attorney fees and costs.

34. On information and belief, Defendants intend to continue their unlawful infringing activity, and PRN continues to and will continue to suffer irreparable harm – for which there is no adequate remedy at law – from such unlawful infringing activity unless Defendants are enjoined by this Court.

COUNT II

INFRINGEMENT OF U.S. PATENT NO. 9,381,183

35. PRN re-alleges and incorporates by reference the allegations set forth in paragraphs 1 through 34.

36. PRN is the owner of all right, title and interest in the '183 Patent.

37. The invention described and claimed in the '183 Patent is directed to methods for improving the quality of the meibum composition of inflamed or dysfunctional meibomian glands, comprising the steps of: (1) administering an effective amount of omega-3 fatty acids on a daily dosage basis, wherein the omega-3 fatty acids include eicosapentaenoic acid (EPA) in an amount greater than

600 mg and comprising the triglyceride form; (2) increasing levels of anti-inflammatory omega-3's in a composition of meibum of the treated meibomian glands and (3) decreasing levels of inflammatory omega-6's in the composition of meibum. The methods of the present invention may further comprise the steps: (1) improving tear break up time; (2) reducing tear osmolarity and/or (3) improving the quality of tears associated with conditions of dry eye, blepharitis and/or meibomianitis.

38. A copy of a product advertisement for the TEAR SUPPORT PLUS + product as advertised on www.amazon.com is attached as Exhibit C. Referring to page 4, under the header "Product description," it reads, as follows:

> Lunovus' Tear Support Plus, Dry Eye Formula not only contains the essential ingredients proven to benefit dry eye, it is also one of the most affordable pharmaceutical grade products. Lunovus's Tear Support Plus, Dry Eye Formula could help to reduce dry eye symptoms, including burning, stinging, redness and intermittent visual disturbances. For this reason, many eye doctors are now recommending Lunovus's Tear Support Plus, Dry Eye Formula for their patients who suffer from dry eyes. Recent studies have found that certain combinations of vitamins, minerals, and Omega-3 fatty acids tend to decrease inflammation and improve tear gland secretions. Lunovus's Tear Support Plus, Dry Eye Formula has specific dosages of key ingredients to help maximize dry eye relief. We developed this formula to treat the core of the problem from the inside out. Many patients may find that they no longer need re-wetting drops although we recommend using both Lunovus's Tear Support Plus, Dry Eye Formula in tandem with the re-wetting drops for maximum benefit.

39. Upon careful review of the Product description of the TEAR SUPPORT PLUS + product, it is clear that Lunovus contends that its TEAR SUPPORT PLUS + product "not only contains the essential ingredients proven to benefit dry eye, it is also one of the most affordable pharmaceutical grade products." In addition, Lunovus asserts that its TEAR SUPPORT PLUS + product "has specific dosages of key ingredients to help maximize dry eye relief."

40. Upon review of the "Supplement Facts" for the infringing TEAR SUPPORT PLUS + product (*see* Exhibit C), it is clear that the formulation of the TEAR SUPPORT PLUS + product includes the identical ingredients and dosage amounts as compared to the ingredients and dosage amounts of the formulation of the compositions disclosed and claimed in the '183 Patent (*see* Exhibit D) for addressing conditions associated with dry eye.

41. Defendants have been and/or are directly infringing and/or inducing infringement of and/or contributorily infringing the '183 Patent by, among other things, making, using, offering to sell or selling in the United States, or importing into the United States, products that are covered by at least one or more claims of the '183 Patent, including, by way of example and not limitation, the TEAR SUPPORT PLUS + product.

42. The activities of Defendants have caused and will continue to cause substantial damage, including lost revenues, to PRN and irreparable injury for which

PRN has no adequate remedy at law. PRN derives substantial revenues from its products that fall within the scope of one or more claims of the ’183 Patent. PRN has expended considerable sums of money in developing and marketing this technology. The existence in the market of the Lunovus’ TEAR SUPPORT PLUS + product is causing, and will in the future cause, substantial damage to PRN. In order to prevent further irreparable harm, PRN seeks a preliminary and permanent injunction and requests that the Court promptly schedule a trial on the merits.

43. Upon information and belief, Defendants’ infringement of one or more of the ’183 Patent is willful and deliberate, entitling PRN to enhanced damages and reasonable attorney fees and costs.

44. On information and belief, Defendants intend to continue their unlawful infringing activity, and PRN continues to and will continue to suffer irreparable harm – for which there is no adequate remedy at law – from such unlawful infringing activity unless Defendants are enjoined by this Court.

COUNT III

FEDERAL UNFAIR COMPETITION FOR FALSE ADVERTISING UNDER THE LANHAM ACT

45. PRN re-alleges and incorporates by reference the allegations set forth in paragraphs 1 through 44.

46. This cause of action arises under §43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

47. On information and belief, Defendants copied the ingredients and dosage amounts of PRN's patented OMEGA BENEFITS® product, sometimes also referred to and promoted as PRN's patented DRY EYE OMEGA BENEFITS product, to produce the infringing TEAR SUPPORT PLUS + product, which assertion is supported by the "Supplement Facts" label for the infringing TEAR SUPPORT PLUS + product (*see* Exhibit C), which includes the identical ingredients and dosage amounts as compared to the ingredients and dosage amounts of the "Supplement Facts" label of PRN's patented OMEGA BENEFITS® product, sometimes also referred to and promoted as PRN's patented DRY EYE OMEGA BENEFITS product (*see* Exhibit D).

48. However, Defendants' advertisement for the infringing TEAR SUPPORT PLUS + product on www.amazon.com recites, under the "Product

description" header – "We developed this formula to treat the core of the problem from the inside out." *See* Exhibit C, page 4. On information and belief, this statement is falsely advertising that Defendants developed the formula for the TEAR SUPPORT PLUS + product, when in fact, the formula was copied from PRN's patented OMEGA BENEFITS® product, sometimes also referred to and promoted as PRN's patented DRY EYE OMEGA BENEFITS product.

49. Defendants' false statement relating to the origination and development of the infringing TEAR SUPPORT PLUS + product formula has caused and is likely to cause confusion, deception, and mistake by creating the false and misleading impression that Defendant independently developed the product formula or that the product is manufactured or distributed by Plaintiff, or are affiliated, connected, or associated with Plaintiff, or have the sponsorship, endorsement, or approval of Plaintiff.

50. Defendants have made false representations, false descriptions, and a false claim that it originated the development of its goods in violation of 15 U.S.C. § 1125(a), and Defendants' activities have caused and, unless enjoined by this Court, will continue to cause a likelihood of confusion and deception of members of the trade and public and, substantial injury to the public and to Plaintiff, and therefore,

Plaintiff is entitled to recover Defendants' profits, actual damages, enhanced profits and damages, costs, and reasonable attorneys' fees pursuant to 15 U.S.C. §§ 1125(a) and 1117.

COUNT IV

ALABAMA COMMON LAW UNFAIR COMPETITION

51. PRN re-alleges and incorporates by reference the allegations set forth in paragraphs 1 through 50.

52. This cause of action arises under the Alabama common law of unfair competition.

53. Defendants' false representations, false descriptions, and a false claim that it originated the development of its goods has caused and is likely to cause confusion, deception, and mistake by creating the false and misleading impression that Defendants independently developed the product formula or that the product is manufactured or distributed by Plaintiff, or are affiliated, connected, or associated with Plaintiff, or have the sponsorship, endorsement, or approval of Plaintiff.

54. By committing the acts alleged herein, Defendants are guilty of unfair competition and false advertising, in violation of the Alabama common law of unfair

competition, causing a likelihood of confusion and deception of members of the trade and public and, substantial injury to the public and to Plaintiff. Plaintiff is entitled to recover Defendants' profits, actual damages, enhanced profits and damages, costs, and reasonable attorneys' fees to the extent available at law pursuant to Alabama common law of unfair competition.

COUNT V

STATE STATUTORY UNFAIR COMPETITION AND UNFAIR AND DECEPTIVE BUSINESS AND TRADE PRACTICES

55. PRN re-alleges and incorporates by reference the allegations set forth in paragraphs 1 through 54.

56. Defendants have been and continue selling and offering for sale goods that unlawfully infringe both the PRN Patents and Defendants have made and continue to make false representations, false descriptions, and a false claim that it originated the development of its goods, which has caused and is likely to cause confusion, deception, and mistake by creating the false and misleading impression that Defendants independently developed the product formula or that the product is manufactured or distributed by Plaintiff, or are affiliated, connected, or associated with Plaintiff, or have the sponsorship, endorsement, or approval of Plaintiff.

57. On information and belief, Defendants' conduct constitutes unfair competition and unfair and deceptive trade and business practices in violation of the laws of several states, including but not limited to, California Business and Professional Code, § 17200 *et seq*.; Texas Deceptive Trade Practices - Consumer Protection Act, §17.46; Massachusetts Unfair Competition Law, M.G.L. c.93A § 2; and the Utah Unfair Competition Act, Title 13 Chapter 5a § 102.

58. By committing the acts alleged herein, Plaintiff is entitled to recover Defendants' profits, actual damages, enhanced profits and damages, costs, and reasonable attorneys' fees pursuant to the laws and codes of all state laws violated, including those listed.

DEMAND FOR JURY TRIAL

59. Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, PRN respectfully requests a trial by jury of all issues properly triable by jury.

PRAYER FOR RELIEF

WHEREFORE, PRN prays for relief and requests judgment against Defendants as follows:

A. For a judgment declaring that Defendants have infringed each of the PRN Patents;

B. For a judgment awarding PRN compensatory damages as a result of Defendants' infringement of the PRN Patents in an amount not yet calculated, together with interest and costs, but in no event an amount less than $150,000;

C. For a judgment declaring that Defendants' infringement of the PRN Patents has been willful and deliberate;

D. For a judgment awarding PRN treble damages and pre-judgment interest under 35 U.S.C. § 284 as a result of Defendants' willful and deliberate infringement of the PRN Patents;

E. For a judgment declaring that this case is exceptional and awarding PRN its expenses, costs and attorneys' fees in accordance with 35 U.S.C. §§ 284 and 285 and Rule 54(d) of the Federal Rules of Civil Procedure;

F. For a grant of a permanent injunction pursuant to 35 U.S.C. § 283, enjoining the Defendants from further acts of infringement;

G. For a judgment declaring the Defendants falsely advertised the development and origination the TEAR SUPPORT PLUS + product;

H. For a judgment awarding Defendants' profits, actual damages, enhanced profits and damages, costs, and reasonable attorneys' fees to the extent available at law pursuant to 15 U.S.C. §§ 1125(a) and 1117 and Alabama common law of unfair competition.

I. For such other and further relief as the Court deems just and proper.

/s/ Marcus R. Chatterton
One of the Attorneys for Plaintiff, Physicians Recommended Nutriceuticals

Dated: June 9, 2017
OF COUNSEL:

Will Hill Tankersley
Marcus R. Chatterton
BALCH & BINGHAM LLP
Post Office Box 306
Birmingham, AL 35201-0306
Telephone: (205) 251-8100
Facsimile: (205) 488-5872
E-mail: wht@balch.com
E-mail: mchatterton@balch.com

Gary D.E. Pierce (*pro hac vice to be filed)*
PIERCE IP LAW, PLLC
Wells Fargo Center
299 S. Main Street, Suite 1300
Salt Lake City, UT 84111
Telephone: (801) 535-4678
Facsimile: (866) 514-6015
Email: gpierce@pierceiplaw.com

Karl R. Cannon (*pro hac vice to be filed*)
CLAYTON, HOWARTH & CANNON, PC
6985 Union Park Center, Suite 200
Cottonwood Heights, UT 84047
Telephone: (801) 255-5335
Facsimile: (801) 255-5338
Email: kcannon@chcpat.com

VERIFICATION OF COMPLAINT

I, Michael B. Gross, MD, am the Senior Vice President and Chief Medical Officer of Plaintiff Physicians Recommended Nutriceuticals, LLC, and I do hereby state and assert that the facts and allegations contained herein are true, except so far as they are stated to be on information and belief, and that, so far as they are therein stated to be on information and belief, I believe them to be true.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 31 day of May, 2017

Michael B. Gross, MD
Senior Vice President and Chief Medical Officer
Physician Recommended Nutriceuticals, LLC

CERTIFICATE OF SERVICE

Plaintiff will serve a filed copy of the foregoing complaint, via private process server, on the following:

LUNOVUS
8289 Highway 31 N.
Morris, Alabama 35116

/s/ Marcus R. Chatterton
OF COUNSEL